



**UNITED STATES DEPARTMENT OF COMMERCE**  
**United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/444,221 11/19/99 MURPHY

B 17634-000513

EXAMINER

HM22/0517

TOWNSEND AND TOWNSEND AND CREW LLP  
TWO EMBARCADERO CENTER  
8TH FLOOR  
SAN FRANCISCO CA 94111-3834

BRUMBACK, R

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/444,221

Applicant(s)

Murphy et al.

Examiner

Brenda Brumback

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 12, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63-147 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 63-147 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1642

### **DETAILED ACTION**

1. Responsive to the communication of 04/12/2001, in which applicant pointed out that the Restriction Requirement of 02/09/2001 was not directed to the currently pending claims subsequent to a preliminary amendment filed on 03/21/2000, the previous Restriction Requirement is withdrawn in view of the new requirement which follows.

#### ***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 63-76 and 90-145, drawn to an isolated respiratory syncytial virus (RSV) or polynucleotide comprising a modification of a cis-acting regulatory sequence which is a GS or GE signal or introduction of a translation termination codon, classified in class 424, subclass 211.1 or class 536, subclass 23.1.
  - II. Claims 63 and 77-145, drawn to an isolated RSV or polynucleotide comprising a modification of a cis-acting regulatory sequence which is a RSV promotor element or introduction of a translation termination codon, classified in class 424, subclass 211.1 or class 536, subclass 23.1.
  - III. Claims 146 and 147, drawn to a method for producing an infectious RSV from one or more isolated polynucleotide molecules, classified in class 536 subclass 23.1 or in class 435, subclass 320.1.

Art Unit: 1642

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polynucleotides of Groups I and II can be used in the materially different process of diagnostic testing.

The RSV and polynucleotides of Groups I and II have different structures and different biological characteristics.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 63, 127, and 146 are generic to a plurality of disclosed patentably distinct species comprising

an isolated recombinant RSV with a modification of a cis-acting regulatory sequence and  
an isolated recombinant RSV with an introduction of a translation termination codon.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of these claims, even though this requirement is traversed. Should applicant traverse on the ground that

Art Unit: 1642

the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- Also applied to claims 90 - 130*
6. Claims 131- 145 are generic to a plurality of disclosed patentably distinct species of further modifications comprising
- a partial or complete gene deletion,
  - a change in gene position or altering the position of one or more genes relative to an RSV promoter
  - a frame shift mutation,
  - one or more nucleotide changes that modulate expression of a selected gene through introduction of one or more translation termination codons,
  - one or more nucleotide changes that modulate expression of a selected gene through introduction, modification, or ablation of a translational start site,
  - an attenuating mutation specifying an amino acid substitution at Val 267 in the RSV N gene,
  - an attenuating mutation specifying an amino acid substitution at Glu218 or Thr523 in the RSV F gene,

Art Unit: 1642

an attenuating mutation specifying an amino acid substitution at Cys319, Phe521, Gln831, Met1169, Tyr131, or His1690 in the RSV polymerase gene L,  
a nucleotide substitution in the gene-start sequence of M2,  
a polynucleotide encoding a chimeric RSV from human subgroup A and human subgroup B,  
a polynucleotide encoding chimeric human/bovine RSV,  
a polynucleotide encoding chimeric RSV/PIV,  
a polynucleotide encoding a cytokine,  
a polynucleotide encoding a T-helper epitope, and  
a polynucleotide encoding a protein of a microbial pathogen.

Applicant is **also** required under 35 U.S.C. 121 to elect a single disclosed species of these claims, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1642


7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

May 17, 2001

  
Brenda Brumback,  
Patent Examiner